Remarks

Claims 1-19 and 22 are pending in the present application. Claims 1-19 and 22 are rejected and claims 20-21 are cancelled. By the present amendment, claims 1, 10 and 12 are amended and claim 7 is cancelled.

Rejections Pursuant to 35 U.S.C. §102(b)

In the Office Action, claims 1-3, 9-12 and 14-18 are rejected under 35 U.S.C. §102(b) as being anticipated by Brody et al. (U.S. Patent No. 5,922,210). In addition, claims 1-6, 8, 9, 12-14 and 18 are rejected under §102(b) as being anticipated by Winkelman (U.S. Patent No. 3,596,652), and claims 12 and 19 are rejected under §102(b) as being anticipated by Rapoza et al. (U.S. Patent No. 3,832,969).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Claim 7 is cancelled herein and its subject matter has been incorporated into amended claims 1, 10 and 12, which now each recite, *inter alia*, a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Support for this amendment appears in the claims as originally filed and throughout the specification. No new matter has been added.

Brody et al., Winkelman and Rapoza et al. do not describe the subject matter of amended independent claims 1, 10 and 12 and, therefore, cannot be relied upon in support of the instant rejections (these patent references were not cited as teaching the subject matter of claim 7). Claims 2-6 and 8-19 contain all of the limitations of the base claim from which they depend. Accordingly, applicants respectfully request the rejections based on Brody et al., Winkelman and Rapoza et al. be withdrawn.

Also in the Office Action, claims 1 and 7 are rejected under 35 U.S.C. §102(b) as being anticipated by Ayres (U.S. Patent No. 3,897,340). It is asserted in the Office Action, in support of the instant rejection, that Ayres discloses a device for separating plasma from whole blood that comprises a first zone separated from a second zone by a piston 18 and two filters 30, 32. It is further asserted that in operation the first zone is filled with whole blood and plasma and only the plasma enters the second zone via filters 30 and 32, and that plasma can be discharged through closure member 15.

As noted above, claim 7 is cancelled herein and its subject matter has been incorporated into independent claim 1 that now recites, *inter alia*, a device for separating and discharging plasma comprising a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone, and a discharge unit configured to act, after plasma separation, substantially on the second zone without the discharge unit having an effect on the first zone so that the separated plasma is released from the second zone and is discharged through an outlet of the device. Ayres however does not teach or suggest this subject matter. Although Ayres discloses two filters, a coarse filter 30 and a fine filter 32, and a piston 18 in a plasma/serum separator assembly 10, he does not disclose a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Ayres further does not teach or suggest a discharge unit configured to act, after plasma separation, substantially on the second zone without the discharge unit having an effect on the first zone so that the separated plasma is released from the second zone and is discharged through an outlet of the device.

In contrast to the subject matter recited in amended claim 1, both filters 30, 32 in the Ayres device serve the purpose of retaining corpuscular blood components – the first or coarse filter 30 serving as a prefilter to take out larger particles such as fibrin strands or clots from the plasma or serum (col. 3, lines 44-47) and the second or fine filter 32 to stop the movement of the piston 18 at the plasma/serum-cellular interface upon becoming clogged by cellular blood components (col. 4, lines 3-9). When the

assembly 10 is subject to centrifugation, the piston 18 moves downwardly in container 12 causing both the coarse and fine filters 30, 32 to be acted on. This is contrary to the subject matter recited in amended claim 1, which defines a discharge unit configured to act, after plasma separation, substantially on the second zone (transport fleece) without the discharge unit having an effect on the first zone (separation fleece) to discharge plasma collected in the second zone. Moreover, in contrast to the present application, Ayres requires that the plasma/serum separator assembly be centrifuged in order to separate whole blood into its components.

For all of the reasons set out above, applicants submit that Ayres cannot be relied upon in support of the instant rejection and respectfully request that the objection be withdrawn.

Rejections Pursuant to 35 U.S.C. §102(e)

Also in the Office Action, claims 1-16, 18 and 19 are rejected under 35 U.S.C. §102(e) as being anticipated by Marsden (U.S. Pat. Appln. Pub. No. 2002/0143298 A1). Independent claims 1, 10 and 12 are amended herein and recite, *inter alia*, a separation element or, with respect to claim 12, providing a separation element, comprising a separation fleece as a first zone and a transport fleece as a second zone. Claims 1 and 10 further recite a discharge unit configured to act, after plasma separation, substantially on the second zone without the discharge unit having an effect on the first zone so that the separated plasma is released from the second zone and is discharged through an outlet of the device, and claim 12 further recites processing the second zone without affecting the first zone such that plasma is released from the second zone, and discharging the released plasma through an outlet. For the following reasons, *inter alia*, applicants respectfully submit that Marsden does not anticipate the subject matter recited in claims 1, 10 and 12.

First, Marsden does not teach a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. It is asserted in support of the instant rejection that Marsden discloses a device comprising "a first zone 10 removably separated from a second zone 64 by filters 81 and 82. The filters are adapted to separate plasma from whole blood when pressure is applied by plunger 34." The first zone 10 cited in the Office Action is a syringe assembly (see Marsden, e.g., Fig. 2 and para. [0036]). Also, the second zone 64 cited in the Office Action is a blunt cannula (see Marsden, e.g., Figs. 4-6 and para. [0039]). Marsden describes a blunt cannula 64 including a filter 80A or 80B that separates cellular components from whole blood as plunger 34 is urged distally to direct a selected volume of collected blood through filter 80A or dual filter 80B. Marsden mentions that filters 80A and 80B normally will be able to produce a sufficient volume of plasma . . . prior to clogging (Marsden at col. 4, para. [0046]).

In accordance with the present application, blood is applied to the first zone (separation fleece), plasma is passed into the second zone (transport fleece), and the remaining blood components are substantially completely retained in the first zone. Marsden, in contrast, does not teach a transport fleece. Filter 80A or 80B separates cellular components from the whole blood that is urged from fluid receiving chamber 22 of syringe body 16. Thus forces of plunger 34 direct a plasma fluid into testing cartridge 12 for analysis. Marsden at col. 4, para. [0046].

In addition, Marsden does not teach or suggest a discharge unit configured to act, after plasma separation, substantially on the second zone without the discharge unit having an effect on the first zone so that the separated plasma is released from the second zone and, with respect to claim 12, does not teach processing the second zone without affecting the first zone such that plasma is released from the second zone. As noted above, Marsden first does not teach a transport fleece as a second zone. Moreover, Marsden separates cellular components from whole blood as plunger 34 is urged distally to direct a selected volume of collected blood through filter 80A or dual

filter 80B. By pressing plunger 34, filter 80A or dual filter 80B are acted on – not a discharge unit configured to act, after plasma separation, substantially on the second zone (transport fleece) without the discharge unit having an effect on the first zone (separation fleece). In accordance with the present invention, the discharge unit does not act on the separation fleece (where red blood cells are retained) because such action would possibly destroy the cells causing hemolysis and possibly setting haemoglobin free which would then infiltrate the plasma in the transport fleece and turn it red, which is to be avoided.

In view of the present amendment and remarks made herein, Marsden cannot be relied upon in support of the instant rejection. Claims 2-6, 8, 9, 11, 13-16, 18 and 19 contain all of the limitations of the base claim from which they depend. Accordingly, applicants respectfully request the rejection be withdrawn.

Rejections Pursuant to 35 U.S.C. §103(a)

Also in the Office Action, claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Marsden. In support of the instant rejection, it is asserted that although Marsden discloses that the plasma separation is assisted by positive pressure and not negative pressure, it would have been obvious to one of ordinary skill in the art to utilize negative pressure instead of positive pressure so that the blood components do not get crushed against the filters by the plunger.

Claim 22 is also rejected under 35 U.S.C. §103(a) as being unpatentable over Marsden in view of Goldberg (U.S. Patent No. 4,226,713). In support of the instant rejection, it is asserted that although Marsden discloses that the plasma can be analyzed, but does not disclose that the analyte to be detected is HDL, in light of the disclosure of Goldberg it would however have been obvious to one of ordinary skill in the art to use the method disclosed by Marsden to determine the HDL concentration in the plasma.

Claim 12 is amended herein and recites a method for plasma separation and discharge comprising providing a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone, applying blood to the first zone of the separation element, separating plasma from other blood components by means of the separation element, the blood components being substantially retained in the first zone and the plasma being passed into the second zone of the separation element, processing the second zone without affecting the first zone such that plasma is released from the second zone, and discharging the released plasma through an outlet.

To establish a *prima facie* case of obviousness, *inter alia*, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Claims 17 and 22 are dependent upon claim 12 and therefore contain all of the limitations of that claim. As noted above, Marsden does not teach or suggest the subject matter of amended claim 12 - providing a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone and, processing the second zone without affecting the first zone such that plasma is released from the second zone. In view of the amendment made herein, Marsden cannot be relied upon in support of the instant rejection. Applicants respectfully request that the rejection be withdrawn.

Also in the Office Action, claims 10, 11 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Winkelman. In support of this rejection, it is asserted in the Office Action that although Winkelman does not explicitly disclose a test element, the reference does disclose that the device is intended to be used for isolating the plasma for analysis and, it would have been obvious to one of ordinary skill in the art to provide the device disclosed by Winkelman with a test element for analyzing the plasma. With respect to claim 15, it is further asserted although the reference does not explicitly disclose that the separated plasma is released from the second zone by means of pressure, given that the second zone is a syringe-like device, it would have been obvious to one of ordinary skill in the art to remove the plasma from the second

zone by means of pressure as it is well-known in the art to remove the contents of a syringe via pressure.

Claim 22 is also rejected under 35 U.S.C. §103(a) as being unpatentable over Winkelman in view of Goldberg (U.S. Patent No. 4,226,713). In support of the instant rejection, it is asserted that although Winkelman discloses that plasma can be analyzed, but does not disclose that the analyte to be detected is HDL, in light of the disclosure of Goldberg it would however have been obvious to one of ordinary skill in the art to use the method disclosed by Winkelman to determine the HDL concentration in the plasma to ascertain the risk factors associated with coronary heart disease.

As noted previously herein, claim 7 is cancelled and its subject matter has been incorporated into amended claims 1, 10 and 12, which now each recite, *inter alia*, a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Winkelman was not cited in support of the rejection of claim 7 and, therefore, cannot be relied upon here in support of the rejection of amended claim 10, which includes that subject matter. Winkelman does not teach or suggest a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Because in order to support a *prima facie* case of obviousness the prior art reference must teach or suggest all the claim limitations, applicants submit that Winkelman cannot be relied upon in support of the instant rejection. Claim 11 depends directly from claim 10, and claims 15 and 22 depend from claim 12, which also recites a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. MPEP 2143.03 (*citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Accordingly, applicants respectfully request that the rejection be withdrawn.

Finally, in the Office Action, claims 7, 16 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Winkelman in view of Ayres. In support, the

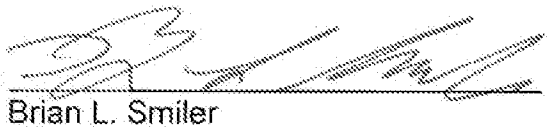
Examiner asserted the device disclosed by Winkelman does not comprise a fleece to isolate the plasma, but instead relies on precise movement of the plunger to prevent blood components from entering the second zone. However, the Examiner further asserted Ayres discloses a device for separating plasma from whole blood wherein the separation is accomplished by means of two filters 30 and 32 and, in light of Ayres, it would have been obvious to one of ordinary skill in the art to provide the device disclosed by Winkelman with filters and to filter the blood to provide a simpler and accurate means to prevent blood components from entering the second zone.

Claim 7 is cancelled herein and its subject matter has been incorporated into amended claims 1, 10 and 12, which now each recite, *inter alia*, a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Claims 16 and 17 are dependent upon claim 12. Ayres does not fulfill the deficiencies of Winkelman, as neither reference teaches or suggests a separation element comprising a separation fleece as a first zone and a transport fleece as a second zone. Ayres and Winkelman, either alone or in combination, further do not teach or suggest a discharge unit configured to act, after plasma separation, substantially on the second zone without the discharge unit having an effect on the first zone so that the separated plasma is released from the second zone and is discharged through an outlet of the device. For at least these reasons, Ayres and/or Winkelman cannot be relied upon in support of the instant rejection. In light of the present amendment, applicants respectfully request that the rejection be with withdrawn.

Conclusion

Applicants have filed a complete response to the outstanding Office Action and respectfully submit that, in view of the above amendments and remarks, the application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,
ROCHE DIAGNOSTICS OPERATIONS, INC.

By 
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